non-porous. The thinness, flexibility and strength of the construction allows the resulting balloon to be collapsed to a small. First diameter for insertion into the vasculature to a desired location at which it can be inflated to the maximum diameter of the tube in the fashion of a conventional polethylene terephthalate (PET) catheter balloon. The balloon of the present invention is superior to such conventional balloons again due to its flexibility, thinness, strength and lubricious materials.

III. REJECTION OF CLAIMS 1-9 UNDER THE JUDICIALLY CREATED DOCTRINE OF DOUBLE PATENTING OVER CLAIMS 1-22 OF US PATENT 6,027,779, CLAIMS 1-40 OF US PATENT 6,025,044 AND CLAIMS 1-2 OF US PATENT 6,027,811

The present application is assigned to the same entity as the cited issued patents. A terminal disclaimer is submitted herewith as necessary to resolve the double patenting rejection.

IV. REJECTION OF CLAIMS 1-5 AND 8-9 UNDER 35 USC 102(b) AS ANTICIPATED BY BUCK et al., US PATENT 4,925,710.

The Examiner states that Buck et al. disclose a thin-wall non-porous tube comprising porous PTFE and a non-porous coating comprising polymers such as fluorinated ethylene propylene (FEP) and commercially available thermoplastic adhesives such as thermoplastic fluoropolymers. The Examiner further notes that the reference does not disclose the intended use of the PTFE tube as a "catheter balloon" but adds that in the absence of evidence to the contrary or specific structural limitations, the PTFE tube disclosed by the reference anticipates the claim.

The Applicants respectfully disagree with the Examiner's interpretation that the tube of Buck et al. is comprised of porous PTFE. There is no evidence of this in the entire specification. The PTFE is of Buck et al. is described as optionally containing fillers such as spherical glass beads (e.g., col. 4, lines 48-57). While the resulting tube contains materials other than PTFE and may indeed contain voids fully enclosed within the spherical glass beads, there is absolutely no indication that the resulting tube is porous through its wall. Indeed, Buck et al. teach away from the use of fillers that are volatile or leachable which might be used to achieve a truly porous tube; see col. 4, lines 9-10.

It is the porosity of the porous expanded PTFE (ePTFE) used as the substrate of the claimed catheter balloon that provides the excellent flexibility combined with high strength in a thin tube that allows the balloon to be collapsed to a small size and subsequently inflated to its full diameter within a body conduit. The non-porous coating provided over the strong, thin and flexible porous PTFE substrate allows the ePTFE tube to be used as a catheter balloon capable of containing an inflation media such as saline fluid. The rigid filler components of the PTFE tube of Buck et al. will result in a tube that is inadequately flexible for use as a catheter balloon.

The present claims are amended to describe that the tube provides the necessary behaviorial characteristics necessary for use as a catheter balloon, i.e., that the tube is adequately flexible to be readily collapsible to a small size from which it can be subsequently inflated to the full diameter of the tube. Buck et al. do not teach or suggest the use of porous PTFE, nor do they teach or suggest in any fashion a catheter balloon as presently claimed.

V. REJECTION OF CLAIMS 1-9 UNDER USC 103(a) AS UNPATENTABLE OVER BUCK et al. IN VIEW OF GORE, US 3,593,566 AND SOLTESZ, US 5,254,107.

The Examiner describes that Gore teaches the manufacture of ePTFE and that Soltesz teaches the construction of a tube having a middle layer of wire reinforcement which is enclosed by inner and outer thermoplastic sections wherein the inner section may be PTFE or the like. The catheter tube of Soltesz is expected to be inelastic on the basis of the materials described for use as the Soltesz catheter tube. The claims are rejected as obvious over the combination of the three cited references. In particular, the catheter balloon of claim 7 pertaining to an inelastic balloon is seen as obvious over the inelastic catheter tube of Soltesz.

On the basis of the Applicants' experience with porous and non-porous fluoropolymer tubes made in wide ranges of thicknesses and diameters, for applications ranging from wire insulations to implantable vascular grafts, it is their opinion that the tubes of both Soltesz and Buck et al. are inelastic, meaning that when subjected to a deforming force the material does not recover its pre-deformation dimensions following the release of that force. Elastic catheter balloons are typically constructed of materials such as latex and behave in the manner of rubber balloons. Their cross section in a collapsed state is generally the same as in their inflated, larger diameter state due to the elastic character of the material. They are generally not capable of withstanding the higher inflation pressures used with inelastic balloons of, for example, PET. Such inelastic balloons are generally provided in a collapsed state wherein the balloon material is folded (see Figure 14A of the present application). The circumference of the inelastic balloon (the distance around the balloon surface measured transversely to the length of the balloon) is thus constant regardless of whether the balloon is collapsed or inflated. These balloon are capable of withstanding high inflation pressures and as such are particularly useful for balloon angioplasty wherein hard athlerosclerotic lesions within a blood vessel are fractured enabling the passageway to be reopened. They are also used to deploy balloon expandable stent devices.

As has been described above, Buck et al. teach a thinwall fluoropolymer tubing that does not provide the necessary characteristics (e.g., flexibility) for use as an inelastic balloon. Gore teaches the manufacture of ePTFE generally but does not teach or suggest how to modify the material for use as a catheter balloon, much less make any suggestion to so use the material.

Soltesz' catheter tubing, while certainly inelastic, also lacks the necessary flexibility for possible use as a catheter balloon. The man of skill would have no reason to consider any of these references if he intended to make a strong and thin catheter balloon. Further, there is no suggestion to combine the references. Finally, the combined references do not result in the claimed invention as described by the claims as now amended.

CONCLUSION

The applicants believe that their claims as amended are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully Submitted,

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